510(k) Summary

PROTEUS™ PTA Catheter with Embolic Capture Feature

Introduction

This document contains the 510(k) summary for the modified PROTEUS™ PTA Catheter with Embolic Capture Feature. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Applicant Name and Address:

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DEC 0 6 2013

Summary Preparation Date: September 24, 2013

Device Name and Classification:

Trade Name:	PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature
Common Name:	Percutaneous Transluminal Angioplasty Balloon Catheter
Classification Name:	Catheter, Percutaneous
Classification:	Class II, 21 CFR 870.1250
Product Code	LIT

Angioslide Ltd. - Traditional 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
Section 7: 510(k) Summary

Predicate Devices:

The modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is claimed to be substantially equivalent to the following legally marketed predicate device:

- Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature (K120805)

Performance Standards: There are no mandatory performance standards for this device.

Device Description (see Figure 1)

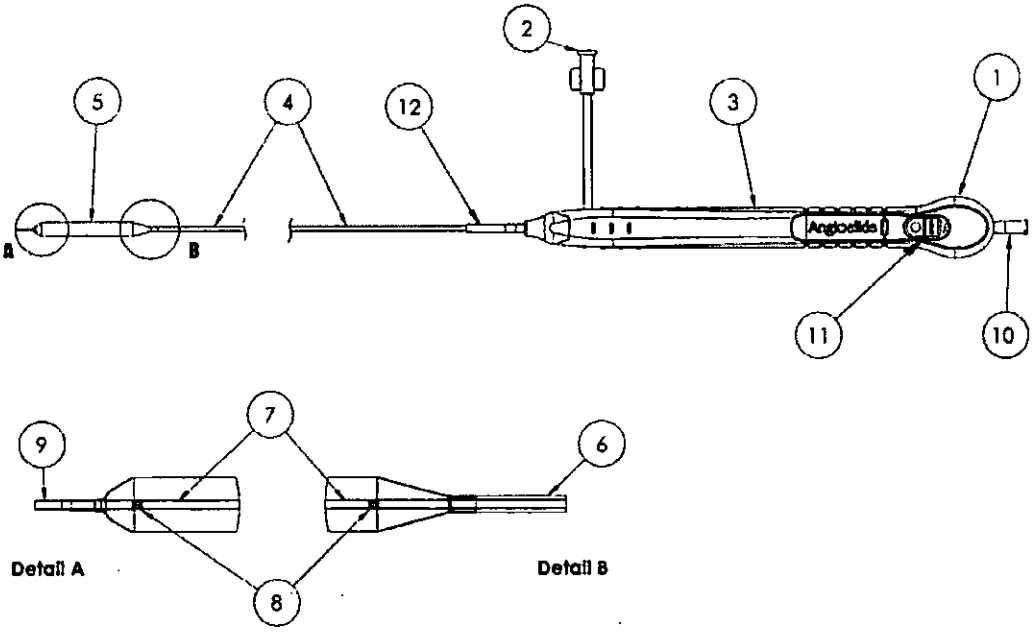

Figure 1

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is an over the wire dual lumen catheter with a foldable balloon (5) located near the distal atraumatic soft tip (9).

One lumen is used for inflation of the balloon and is accessed via the inflation port (2). The other lumen, starting at the guidewire port (10), allows access to the distal tip for guidewire insertion (max. 0.035"). The balloon has two radiopaque markers (8) for positioning the balloon relative to stenosis. The radiopaque markers indicate the dilating section of the balloon and help in balloon placement. The balloon is designed to provide an inflatable segment of known diameter and length at specified pressure.

The shaft (4) comprises the outer shaft (6) and the inner shaft (7). The distal end of the balloon (A) is connected to the inner shaft and the proximal end of the balloon (B) is connected to the outer shaft. The inner shaft is connected to the proximal hub (10) which is connected to the pulling knob (1) and the outer shaft is connected to the handle grip (3). The pulling knob lock (11) locks the handle grip and the pulling knob together. The distal end of the balloon is folded inwards towards the proximal end of the balloon, by pressing on pulling knob lock (11) and pulling the pulling knob away from the handle (1). The inward-folding of the balloon forms a cavity and allows for collection and removal of embolic material.

The balloon size and diameter are printed on the strain relief (12). Refer also to the package label for information about catheter length, balloon nominal and rated burst pressure, balloon size, balloon compliance, guidewire compatibility and sheath compatibility.

Indications for Use:

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and removal of embolic material (e.g. debris, thrombus) during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Comparison of Modified Indications for Use

The modified indications for use clarifies the device functionality of the PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature. The modification of the phrase "capture and containment" to "capture and removal" in the Indications for Use is intended only to clarify the device's functionality and to accurately convey that functionality to the user. The technology of the device not only captures the embolic material in a closed cavity, but also provides corresponding removal after angioplasty of peripheral vasculature. There is no option for the containment of embolic material without its immediate subsequent removal.

The modified indications for use also serves to clarify the types of embolic material that the device is capable of capturing and removing, i.e. debris and thrombus. The clinical study (MC-LEADER) supporting the device's original clearance in K090364 provides evidence of the embolic material (debris and thrombus) that the device successfully and effectively captured and removed from the subject's peripheral vasculature.

The modified indications for use statement for the PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process as compared to the predicate device PROTUES™ PTA Balloon Catheter (K120805).

The unmodified PROTEUS™ PTA Balloon Catheter (K120805) is also indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty. Therefore, the subject device, the PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature, is substantially equivalent to the predicate device.

Angioslide Ltd. - Traditional 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
Section 7: 510(k) Summary

Comparison of Technological Characteristics

The modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over the wire co-axial dual lumen catheter with a foldable balloon located near the distal atraumatic soft tip. The catheter is compatible with a 0.014" (3x100mm only) and 0.035" guide wire.

The balloon catheter technological characteristics of the modified PROTEUS™ PTA Balloon Catheter are identical to those of the unmodified PROTEUS™ PTA Balloon Catheter (K120805). In both devices, lesion dilation is achieved by means of an inflatable balloon.

The modified PROTEUS™ PTA Balloon Catheter overall length, catheter sheath sizing, balloon diameter, balloon length, balloon nominal pressure, balloon rated burst pressure and end hole diameter are the same as those of the unmodified PROTEUS™ PTA Balloon Catheter (K120805).

The embolic capture technological characteristics of the modified PROTEUS™ PTA Balloon Catheter are identical to those of the unmodified PROTEUS™ PTA Balloon Catheter (K120805). In both devices, the capture and removal of embolic material is achieved by proximal vessel occlusion, by means of an inflatable balloon, and subsequent aspiration of embolic material.

Summary of Additional Modifications

In addition to the modifications to the Indications for Use described above, Angioslide has also made the following additional modifications to the PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature:

- Corresponding to the addition of examples of embolic material (e.g. debris, thrombus) in the Indications for Use, the addition of the following warning: "The safety and efficacy of this device has not been evaluated for use in primary embolectomy or primary thrombectomy procedures."
- Removal of the stent-related contraindications for the device ("post-delivery dilation of peripheral vascular stent" and "any vessel containing multiple overlapping stents")
- Miscellaneous labeling revisions

The additional modifications described above do not result in any substantial change to the device's intended use, fundamental scientific technology or principle of operation. Angioslide is not seeking a primary embolectomy or primary thrombectomy claim; therefore, the warning is a risk mitigation for the user mistakenly assuming the device can be used for primary embolectomy and primary thrombectomy based on the examples of embolic material provided in the modified Indications for Use statement. The stent-related contraindications are being removed based on successful design verification and validation demonstrating the device to perform safely and effectively in a stent environment.

The miscellaneous labeling revisions are minor revisions for clarity and, based on regulatory analyses, do not require a new 510(k) submission. However, the minor labeling changes are described in this submission for completeness.

Angioslide Ltd. - Traditional 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
Section 7: 510(k) Summary

Summary of Non-Clinical Testing

In vitro bench testing of the Angioslide PROTEUS™ PTA Balloon Catheter was conducted in accordance with Angioslide's Risk Analysis and all applicable FDA Guidance documents and ISO standards, including:

ISO 10555-1 – *Sterile, Single Use Intravascular Catheters- Part 1: General Requirements*

ISO 10555-4 – *Sterile, Single Use Intravascular Catheters- Part 4: Balloon Dilatation Catheters*

FDA Guidance – Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, April 18, 2010

FDA Guidance – Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions, February 15, 2008

FDA Class II Special Controls Guidance – Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010

All bench testing, unless otherwise specified, was conducted using finished devices which were sterilized by the final validated sterilization process.

Design Verification and Validation:

In order to support the removal of the two contraindications, "post-delivery dilatation of peripheral vascular stents" and "any vessel containing multiple overlapping stents," the aforementioned international standards and FDA guidance documents were followed. Representative devices were chosen specifically based on the details of the change being evaluated, i.e. device performance within a stent environment. Due to the fact that the only change to be evaluated is device performance within a stent environment, individual stent length has no impact. Therefore, each test utilized multiple stents of equivalent diameter to simulate the worst case stent environment, which were selected based on the balloon diameter to be tested.

Sample sizes used for Design Verification and Validation testing were based on required confidence / reliability levels as a result of risk analysis performed for the PROTEUS™ PTA Balloon Catheter, or per recommendations within the FDA Guidance "Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems." Specifically, the number of samples utilized for each test depended on whether the data to be collected was variable data or attribute data in nature.

PROTEUS™ PTA Balloon Catheter Design Verification and Validation Summary Table

Test	Accept/Reject Criteria	Results
Post-Dilatation, Minimum Balloon Burst Pressure (RBP)	▪ RBP ≥ 14atm (3x100 only), 12atm for all other sizes ▪ 95% Confidence, 99.9% Reliability	PASS
Post-Dilatation, Balloon Fatigue (Repeated Inflation / Deflations)	▪ Inflation/Deflation Cycles ≥ 10 at 14atm (for 3x100 only), 12atm for all other sizes ▪ No leakage, rupture, and/or herniation ▪ Up to max 40 cycles ▪ 95% Confidence, 90% Reliability	PASS
Post Dilatation Balloon Inflation/Deflation Testing	▪ Inflation time: ≤ 14.0 sec ▪ Deflation time: ≤ 30.6 sec ▪ No leakage upon inflation ▪ 90% Confidence, 90% Reliability	PASS
Post Dilatation, Simulated Use in Tortuous Anatomy Model – Guide Wire Compatibility	▪ Catheter can be mounted over a 0.014" guide wire (3x100 only), 0.035" guide wire for all other sizes ▪ 90% Confidence, 90% Reliability	PASS
Post Dilatation Simulated Use in Tortuous Anatomy Model – Introducer Sheath Compatibility	▪ Completely folded balloon passes through identified Introducer Sheath (5F, 6F, 7F) at the end of procedure ▪ 90% Confidence, 90% Reliability	PASS
Post Dilatation Simulated Use in Tortuous Anatomy Model – Kink Resistance	▪ No permanent deformations (kinks) are present once removed from the tortuous anatomy model ▪ 90% Confidence, 90% Reliability	PASS
Post-Dilatation Capture Efficiency	▪ N/A – Characterization only	PASS

The effects of using the PROTEUS™ PTA Balloon Catheter within a stent environment were specifically evaluated during verification and validation. The results of the specified testing showed that use within a stent environment with multiple overlapping stents had no adverse impact on balloon performance or clinical use characteristics of the device. All simulated use testing showed equivalent results to the predicate product family used without stents and no performance issues were raised during this testing.

Comparative Capture Efficiency (CE) Testing:

To ensure compatibility of results, the testing approach was identical to that used to gather baseline data submitted in the original 510(k) for the PROTEUS™ PTA Balloon Catheter device family (K90364). The CE testing for the modified PROTEUS™ PTA Balloon Catheter was conducted with multiple overlapping stents in order to evaluate the device's embolic capture performance against the embolic capture performance of the unmodified PROTEUS™ PTA Balloon Catheters, which were previously tested without stents.

The 3x100mm balloon catheter was utilized to characterize the total capture performance of the Angioslide PROTEUS™ PTA Balloon Catheter within multiple overlapping stents. The overall CE test results were consistent with values seen for the previously tested device sizes without multiple overlapping stents. A review of the data in detail revealed no significant anomalies in the raw or analyzed data; and trends in performance based on differences in device size were as expected.

Specifically, prior testing described an overall trend for the Angioslide device of increasing CE as lesion size (length and diameter) increases. This trend is the result of the size of the embolic material capture cavity increasing with increasing balloon length. The combination of this factor and the fact that the Angioslide device does not require additional lesion crossings for deployment causes an increase in CE as device size increases, regardless of the decrease in device diameter. Although there was a slight increase in overall particulate generation for the 3x100mm post-dilatation, the overall capture efficiency remained equivalent. The increase in overall particulate generation was expected due to the addition of multiple overlapping stents within the post-dilatation testing. The consistency of overall capture efficiency with or without multiple overlapping stents was also an expected result due to the direct correlation of lesion length to CE within the Angioslide device.

Biocompatibility Testing:

Based on Risk Analysis no additional biocompatibility testing was required for the modifications described in this submission.

Sterilization:

There have been no changes to the sterilization process for the modified PROTEUS™ PTA Balloon Catheter from its predicate device, K120805; therefore, no sterilization validation was performed.

Packaging:

There have been no changes to the packaging materials or assembly for the modified PROTEUS™ PTA Balloon Catheter from its predicate device, K120805; therefore, no packaging validation was performed.

Shelf Life:

The shelf-life of the modified PROTEUS™ PTA Balloon Catheter is identical to the currently validated three (3) year shelf life for its predicate device, PROTEUS™ PTA Balloon Catheter (K120805). Therefore, no shelf-life validation or accelerated aging tested were performed.

Pyrogenicity:

There have been no changes to the modified PROTEUS™ PTA Balloon Catheter that would affect its validated non-pyrogenic characteristics; therefore, pyrogenicity testing was not required.

Angioslide Ltd. - Traditional 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
Section 7: 510(k) Summary

Substantial Equivalence Discussion:

The following table summarizes and compares data on the Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature cleared in K120805 to the PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature (modified version of the device) that is the subject of this Traditional 510(k) submission.

Specification	Modified Device	Predicate Device (K120805)	Comparison to Predicate
Device Name	Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature	Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature	N/A
Product Code	LIT	LIT, DQY	Substantially Equivalent
Product Classification	870.1250	870.1250	Substantially Equivalent
Product Class	Class II	Class II	Substantially Equivalent
Indications For Use	The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and removal of embolic material (e.g. debris, thrombus) during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries. The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.	The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries. The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.	Substantially Equivalent

Angioslide Ltd. - Traditional 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
Section 7: 510(k) Summary

Specification	Modified Device	Predicate Device (K120805)	Comparison to Predicate
Method of Dilatation	Balloon	Balloon	Substantially Equivalent
Balloon Diameter (mm)	3, 4, 5, 6	3, 4, 5, 6	Substantially Equivalent
Balloon Length (mm)	20, 40, 60, 80, 100	20, 40, 60, 80, 100	Substantially Equivalent
Nominal Pressure (atm)	8	8	Substantially Equivalent
Rated Burst Pressure (atm)	12 / 14 (3x100 only)	12 / 14 (3x100 only)	Substantially Equivalent
Device Visualization	Radiopaque markers	Radiopaque markers	Substantially Equivalent
Method of delivery	Over-the-wire	Over-the-wire	Substantially Equivalent
Useable Length (cm)	135	135	Substantially Equivalent
Sheath size (F)	5, 6, 7	5, 6, 7	Substantially Equivalent
Guide wire compatibility (inch)	0.014 (3x100 only), 0.035	0.014 (3x100 only), 0.035	Substantially Equivalent
Vessel Diameter (mm)	3-6	3-6	Substantially Equivalent
Method of Debris Capture	Foldable balloon, Aspiration	Foldable balloon, Aspiration	Substantially Equivalent
Capture Device placement with respect to lesion	Proximal	Proximal	Substantially Equivalent
Capture Efficiency	73.2% for 3x100mm device post-dilatation	56.1% across product family	Substantially Equivalent

Angioslide Ltd. - Traditional 510(k) PROTEUS™ PTA Catheter with Embolic Capture Feature
Section 7: 510(k) Summary

Specification	Modified Device	Predicate Device (K120805)	Comparison to Predicate
Patient Direct / Indirect Contact Materials	Distal tip – PEBAX Balloon – PEBAX Markers – Platinum/Iridium Shaft – Grilamide	Distal tip – PEBAX Balloon – PEBAX Markers – Platinum/Iridium Shaft – Grilamide	Substantially Equivalent
Sterility	SAL 10^{-6}	SAL 10^{-6}	Substantially Equivalent
Biocompatibility	ISO 10993-1	ISO 10993-1	Substantially Equivalent
Shelf Life	3 years	3 years	Substantially Equivalent

Conclusion:

In conclusion, the modified PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the following legally marketed predicate device:

- PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature, Angioslide – K120805

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Angioslide Ltd.
c/o Mr. Clay Anselmo
Reglera LLC
11925 W. I-70 Frontage Rd. North
Suite 900
Wheat Ridge, CO 80033

Re: K133043
Trade/Device Name: PROTEUS PTA Balloon Catheter with Embolic Capture Feature
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: October 9, 2013
Received: October 10, 2013

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature

Indications For Use:

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and removal of embolic material (e.g. debris, thrombus) during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Bram D. Zuckerman -S
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